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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Steve A. Yon, et al.

Title: SYSTEM AND METHOD FOR INDUCING HYPOTHERMIA WITH ACTIVE PATIENT TEMPERATURE CONTROL EMPLOYING CATHETER-MOUNTED TEMPERATURE SENSOR AND TEMPERATURE PROJECTION ALGORITHM

Serial No.: 10/767,782 Examiner: Not Yet Known

Filed: January 28, 2004 Group Art Unit: 3739

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

The following items are being submitted for this Information Disclosure Statement:

1. X Preliminary Statements
2. X FORM PTO - 1449

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**1. Preliminary Statements**

Applicants cite herewith patents, publications or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made, an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists.

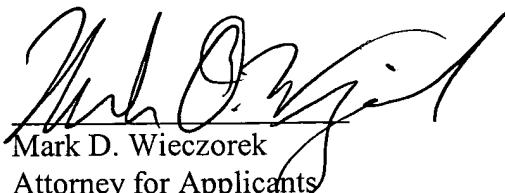
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No fee is believed to be due in connection with this submission as this Information Disclosure Statement is being filed within three (3) months of the application filing date or before receipt of the First Office Action.

However, if any fees are required in connection with this paper, authorization is hereby given to the Commissioner for Patents to charge same to Deposit Account No. 50-0914.

Date: \_\_\_\_\_

Jan. 5, 2005



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Substitute for form 1449B/PTO		JAN 21 2005		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number		10/767,782	
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		First Named Inventor		Yon	
		Group Art Unit		3739	
		Examiner Name		Not Yet Known	
Sheet	1	of	5	Attorney Docket Number 135001	

U.S. PATENT DOCUMENTS						
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publications of Cited document MM-DD-YYYY	Pages, Column, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	6,194,899		Ishihara, et al.	02/27/01	
	A2	20010002442		Dobak, III	05/31/01	
	A3	20010014802		Tu	08/16/01	
	A4	6,303,156		Ferrigno	10/16/01	
	A5	20020032473		Kushnir, et al.	03/14/02	
	A6	20020068877		Abramovitch, et al.	06/06/02	
	A7	4,532,414		Shah et al.	07/30/85	
	A8	5,733,319		Neilson et al	03/31/98	
	A9	4,707,587		Greenblatt	11/17/87	
	A10	5,741,248		Stern et al	04/21/98	
	A11	4,298,006		Parks	11/03/81	
	A12	5,257,635		Langberg	11/02/93	
	A13	4,894,164		Polaschegg	01/16/90	
	A14	5,391,142		Sites et al	02/21/95	
	A15	4,153,048		Magrini	05/08/79	
	A16	4,236,527		Newbower et al	12/02/80	
	A17	4,375,169		Torresin	03/01/83	
	A18	5,861,021		Thome et al	01/19/99	
	A19	20030092975		Casscells, III, et al.	05/15/03	
	A20	20030114903		Ellingboe	06/19/03	
	A21	6,231,594		Dae	05/15/01	
	A22	6,149,673		Ginsburg	11/21/00	
	A23	6,149,676		Ginsburg	11/21/00	
	A24	5,395,331		O'Neill, et al.	03/07/95	
	A25	4,739,492		Cochran	04/19/88	
	A26	4,793,352		Eichenlaub	12/27/88	
	A27	4,796,640		Webler	01/10/89	
	A28	4,819,655		Webler	04/11/89	
	A29	4,871,351		Feingold	10/03/89	
	A30	5,241,951		Mason, et al.	09/07/93	
	A31	5,330,519		Mason, et al.	07/19/94	
	A32	5,437,673		Baust, et al.	08/01/95	
	A33	5,531,776		Ward, et al.	07/02/96	
	A34	5,716,386		Ward, et al.	02/10/98	
	A35	6,296,654		Ward	10/02/01	
	A36	5,891,094		Masterson, et al.	04/06/99	
	A37	6,336,911		Westerbeck	01/08/02	

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Sheet	2	of	5	Attorney Docket Number	135001

	A38	5,403,281	O'Neill, et al.	04/04/95	
	A39	20030014094	Hammack, et al.	01/16/03	
	A40	20040116987	Magers, et al.	01/17/04	
	A41	20020007203	Gilmartin, et al.	01/17/02	
	A42	6,602,243	Noda	08/05/03	
	A43	20030114835	Noda	06/19/03	
	A44	20020077680	Noda	06/20/02	
	A45	6,290,717	Philips	09/18/01	
	A46	20040116988	Hammack, et al.	06/17/04	
	A47	6,702,839	Dae, et al.	03/09/04	
	A48	6,679,906	Hammack, et al.	01/20/04	
	A49	6,299,599	Pham, et al.	10/09/01	
	A50	20010029394	Dobak, III, et al.	10/11/01	
	A51	6,312,452	Dobak, III, et al.	11/06/01	
	A52	20010045104	Bailey, SR., et al.	11/29/01	
	A53	20020111657	Dae, et al.	08/15/02	
	A54	20020193854	Dobak, III, et al.	12/19/02	
	A55	20030060863	Dobak, III, et al.	03/27/03	
	A56	20030088299	Magers, et al.	05/08/03	
	A57	20040030259	Dae, et al.	02/12/04	
	A58	20040087606	Voorhees	05/06/04	
	A59	20040162520	Noda, et al.	08/19/04	
	A60	20040176672	Silver, et al.	09/09/04	

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B1	WO	WO 02/47742		Alsius Corporation	06/20/02		
	B2	WO	WO 00/57823		Alsius Corporation	10/05/00		
	B3	EP	EP0696176B1		Blosense Webster, Inc.	07/03/02		
	B4	EP	EP0428505B2		Gambro Lundia AB	03/14/01		
	B5	WO	WO 01/03606		Alsius Corporation	01/18/01		
	B6	WO	WO 01/10323		Radiant Medical, Inc.	02/15/01		
	B7	WO	WO 02/47742		Alsius Corporation	06/20/02		
	B8	WO	WO 03/006085		Radiant Medical, Inc.	01/23/03		
	B9	WO	WO 03/015673		Innercool Therapies, Inc.	02/27/03		
	B10	WO	WO 04/015382		Radiant Medical, Inc.	02/19/04		
	B12	WO	WO 04/075949		Innercool Therapies, Inc.	09/10/04		

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Sheet	<b>3</b>	of	<b>5</b>	Attorney Docket Number	<b>135001</b>

OTHER PRIOR ART—NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Anon; "Automatic Feedback Instrumentation for Hospital Room Utilizing Microsensors"; IBM Technical Disclosure Bulletin; Vol. 29, No. 3, page 1320 (August 1986).	
	C2	Babbs, Charles F. et al.; "Theoretical Basis for Controlling Minimal Tumor Temperature During Interstitial Conductive Heat Therapy"; IEEE Transactions on Biomedical Engineering, Vo. 37, No. 7; pages 662-672 (July 1990).	
	C3	Behmann, F.W., et al.; "Heat Generation Control during Artificial Hypothermia: I: Experimental Examination of the Influence of Anesthetic Depth"; Pflügers Archiv, Bd. 266, S. 408-421 (1958) (German article with English translation).	
	C4	Behmann, F.W.; "Heat Generation Control during Artificial Hypothermia: II. Theoretical Examinations"; Pflügers Archiv, Bd. 266, S. 422-446 (1958) (German article with English translation).	
	C5	Behmann, F.W.; "Regulation of heat production in experimental hypothermia of homothermal animals"; Naunyn Schmiedebergs Arch Exp Pathol Pharmacol; 228 (1-2): 126-128 (1956). (German article with English translation).	
	C6	Behmann, F.W.; "Heat Generation Control during Artificial Hypothermia, an article about the economic problem of trembling stages"; Pflügers Archive, Vol. 263, pages 166-187 (1956) (German article with English translation).	
	C7	Behmann, F.W., et al.; "Intravascular Cooling, a Method to Achieve Controllable Hypothermia"; Pflügers Archive, Vol. 263, pages 145-165 (1956) (German article with English translation).	
	C8	Benzinger, T.H.; "On Physical Heat Regulation and Sense of Temperature in Man"; Proc. N.A.S.; PHYSIOLOGY; Vol. 45; pages 645-659 (1959).	
	C9	Benzinger MD, Maria; "Tympanic thermometry in surgery and anesthesia"; JAMA; Vol. 209, No. 8; pages 1207-1211 (August 25, 1969).	
	C10	Bone, M.E., et al.; "Bladder Temperature as an Estimate of Body Temperature During Cardiopulmonary Bypass"; Anaesthesia; Vol. 43; pages 181-185 (1988).	
	C11	Cabanac, M; "Selective Brain Cooling and Thermoregulatory Set-Point"; Journal of Basic & Clinical Physiology & Pharmacology; Vol.9, No. 1; pages 3-13 (1998).	

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	C12	Carroll, Diane L., et al.; "A comparison of measurements from a temporal artery thermometer and a pulmonary artery thermistor—preliminary results"; available at <a href="http://pcs.mgh.harvard.edu/CCPD/Nursing_Research/Research_Abstracts_2003.asp#temporal">http://pcs.mgh.harvard.edu/CCPD/Nursing_Research/Research_Abstracts_2003.asp#temporal</a>	
	C13	Dallas, W. Gordon; "Gorman-Rupp Hypothermia Machine"; Health Devices (November 1971-April 1972).	
	C14	DeFord, J. A. et al.; "Design and Evaluation of Closed-Loop Feedback Control of Minimum Temperatures in Human Intracranial Tumours Treated with Interstitial Hyperthermia"; Med. & Biol. Eng. & Comput.; Vol. 29; pages 197-206 (March 1991).	
	C15	Fulbrook, Paul; "Core Body Temperature Measurement: A Comparison of Axilla, Tympanic Membrane and Pulmonary Artery Blood Temperature"; Intensive and Critical Care Nursing; Vol. 13; pages 266-272 (1997).	
	C16	Gentilello MD, L.M.; "Advances in the Management of Hypothermia"; Surgical Clinics of North America; Vol. 75, No. 2; pages 243-257 (April 1995).	
	C17	Gerbrandy et al.; "Oral, Rectal, and Esophageal Temperatures in Relation to Central Temperature Control in Man"; Clin Sci (Lond); Vol. 13, No. 4: pages 615-624. (November 1954).	
	C18	Haley, et al.; "A Randomized Tirilazad Mesylate in Patients with Acute Stroke (RANTTAS). The RANTTAS Investigators"; Stroke; Vol. 27, No. 9; pages 1453-1458 (1996).	
	C19	Hayes, B., et al.; "Temperature Control in Extracorporeal Circulation"; Br Med J. 1968 Aug 17;2(615):430.	
	C20	Hederer, G., et al.; "Animal Experiment Observations Regarding Cardiac Surgery under Intravascular Hypothermia"; Labgebbercs Arch. U. Dtsch. A. Chir., Bd. 283, S. 601-625 (1957) (German article with English translation)	
	C21	Hills, Gordon A., et al.; "Apparatus For Controlling Temperature of Catheter Contents in Cold Environments"; Laboratory Animal Science; Vol. 27, No. 6; pages 1028-1030 (December 1977).	
	C22	Holzman, Steven, et al.; "The Effect of In-Line Microwave Energy on Blood: A Potential Modality for Blood Warming"; Journal of Trauma; Vol. 33, No. 1; pages 89-94 (July 1992).	
	C23	Jackson, Donald, et al; "Hypothermia : IV. Study of Hypothermia Induction Time with Various Pharmacological Agents (24617)"; Proc Soc Exp Biol Med.; 100(2): 332-335 (February 1959).	

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Sheet	<b>5</b>	of	<b>5</b>	Attorney Docket Number	<b>135001</b>

	C24	Kinney, Thomas B, et al.; "Optimizing Myocardial Hypothermia: I. Temperature Probe Design and Clinical Inferences"; Ann Thorac Surg; Vol. 51; pages 278-283 (1991).	
	C26	Lacis, A.T., et al.; "A Device for Surface Cooling and Rewarming in Operations on the "Dry" Heart in Babies and Children During Moderate, Deep and Profound Hypothermia" Aust. N.Z. J. Surg.; Vol. 46, No. 1; pages 29-31 (February 1976).	
	C27	Matsukawa, T. et al.; "Comparison of Distal Oesophageal Temperature with "Deep" and Tracheal Temperatures"; Can J. Anaesth; Vol. 44, No. 4; pages 433-438 (1997).	
	C28	McWilliams, Roger; "Gorman-Rupp Hypothermia Machine"; Gorman-Rupp Industries Division; Health Devices; pages 263-265 (July-August 1972).	
	C29	Moller, P. H. et al.; "Temperature Control and Light Penetration in a Feedback Interstitial Laser Thermotherapy System"; Int. J. Hyperthermia; Vol. 12, No. 1; pages 49-63 (January 1996).	
	C30	Mora, C.T., et al.; "The Effect of Temperature Management During Cardiopulmonary Bypass on Neuropsychologic Outcomes in Patients Undergoing Coronary Revascularization"; The Journal of Thoracic and Cardiovascular Surgery; Vol. 112, No. 2; pages 514-522 (1996).	
	C31	Olshausen, K. et al.; "An Isothermal Flow Meter with Improved Frequency Response for Measuring Tissue Blood Flow"; Pflügers Archive; Vol. 367; pages 97-102 (1976).	
	C32	Shiraki, K., et al.; "Esophageal and Tympanic Temperature Responses to Core Blood Temperature Changes During Hyperthermia"; J Appl Physiol.; Vol. 61, No. 1; pages 98-102 (1986).	
	C33	TE Technology, Inc.; "TE technology/Temperature Controllers" (December 19, 2000) available at: <a href="http://www.tetech.com/temp/tc24-25.html">http://www.tetech.com/temp/tc24-25.html</a>	

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